

REMARKS:

In the Office Action dated February 3, 2010, claims 35-52, in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks. Claims 1-34 have been canceled and claims 35-52 remain in the application.

Claims 35-52 were rejected under 35 USC §112, second paragraph, as indefinite. The claims have been amended to delete the language “derivatives thereof”, and “polymers”. Regarding the term “mineral components”, applicants point out that paragraph [0024] in the published application provides an example of suitable mineral components (silicates and mixtures thereof). Regarding the language “hydrophobic material”, paragraphs [0024] and [0027] in the published application provide examples of hydrophobic materials. In view of this disclosure, one skilled in the art could determine other hydrophobic materials and mineral components suitable for use as a “hard” supporting material. In view of the above amendments, applicants request that this rejection be withdrawn.

Claims 35-52 were rejected on the ground of nonstatutory obviousness-type double patenting as unpatentable over claims 1-11, 13-21 and 23-37 of co-pending Application No. 10/511,885. A terminal disclaimer is enclosed with this response. In view of the terminal disclaimer, applicants request that this rejection be withdrawn..

Claims 35-38, 40-48 and 50-52 were rejected under 35 USC §103(a) as unpatentable over Friedman (2003/0021881) in view of USP 6,312,719 and USP 6,426,069. As pointed out in Applicant's prior response, the matrix of the invention consists only of the supporting material and the acetone insoluble phospholipid, which is the bioactive component. Further

components such as proteins and the ingestible bioactive compound as disclosed by Friedman are not included in the matrix of the present invention. In the present invention, the phospholipid serves as the bioactive compound. Friedman does not describe a hard matrix which consists only of phospholipids and supporting materials and which further shows the dimensions and the respective amounts of bioactive components as indicated in claim 35. Friedman discloses a solid matrix composition comprising functional vegetable proteins, lecithin, and at least one ingestible bioactive compound (see claim 1). The bioactive compound can also be a protein (see page 6, paragraph [0104]). In view of the above amendments, the present claims do not encompass a matrix which includes a protein as in Friedman. USP 6,312,719 and USP 6,426,069 were both cited for the disclosure of lysophosphatidyl choline. Neither of these references suggest or disclose that the proteins used in Friedman can be excluded from the formulation while retaining the desired activity. Applicants respectfully contend that the proteins used in Friedman are an essential part of his composition. Therefore, one skilled in the art would not reformulate Friedman's composition without proteins in view of USP 6,312,719 and USP 6,426,069. In view of the above discussion, applicants request that this rejection be withdrawn.

Claims 35-38, 40-48 and 50-52 were rejected under 35 USC §103(a) as unpatentable over Kiliaan in view of Friedman further in view of USP 6,312,719 and USP 6,426,069. Kiliaan discloses a preparation comprising a long-chain polyunsaturated fatty acid, a phospholipid such as phosphatidyl serine and a compound which is a factor in methionine metabolism such as folic acid, vitamin B12 or vitamin B6 (see claim 1). US 6,312,719 and US 6,426,069 were cited as evidence of the equivalency between phosphatidyl choline and lysophosphatidyl choline. Kiliaan discloses formulations which require a factor in methionine metabolism

and long-chain polyunsaturated fatty acids. These components are essential in Kiliaan but are excluded from the presently claimed invention. Applicants contend that the combination of cited prior art does not suggest the exclusion of components which are essential in Kiliaan and Friedman. In view of the above amendments and comments, applicants request that this rejection be withdrawn.

Claims 35-48 and 50-52 were rejected under 35 USC §103(a) as unpatentable over Kiliaan in view of Friedman further in view of Ponroy. Ponroy was cited as evidence that it would have been obvious for a person skilled in the art to incorporate lysophospholipids into the nutritional preparations of Kiliaan and Friedman for therapeutic benefits such as memory and learning capabilities. None of the Examples in Ponroy et al. disclose the matrix of the present invention consisting only of phospholipids and a supporting material without the proteins used by Friedman or the factor in methionine metabolism and long-chain polyunsaturated fatty acids used by Kiliaan. Thus, Ponroy does not cure the above discussed deficiencies in Kiliaan and Friedman and applicants request that this rejection be withdrawn.

Claim 49 was rejected under 35 USC §103(a) as unpatentable over Friedman in view of USP 6,312,719 and USP 6,426,069 further in view of JP 61078351. JP 61078351 was cited to show that microcapsules comprising lecithin and having a particle size in the range from 10 to 2000 μm are known in the art. JP 61078351 does not disclose the matrix of the present invention consisting only of phospholipids and a supporting material without the proteins used by Friedman and thus does not cure the deficiencies in Friedman in view of USP 6,312,719 and USP 6,426,069 as discussed above. In view of the above amendments and comments, applicants request that this rejection be withdrawn.

Claim 49 was rejected under 35 USC §103(a) as unpatentable over Kiliaan in view of Friedman further in view of USP 6,312,719 and USP 6,426,069 and further in view of JP 61078351. As discussed above, none of the cited prior art, individually or in combination suggests or discloses the matrix of the present invention consisting only of phospholipids and a supporting material without the proteins used by Friedman or the factor in methionine metabolism and long-chain polyunsaturated fatty acids used by Kiliaan. In view of the above amendments and comments, applicants request that this rejection be withdrawn.

Applicants point out that the present inventors have surprisingly found that the matrix according to the invention significantly increases compliance due to the convenient size of the matrix (page 3, last paragraph). In addition, the stability of the phospholipid component is increased by the specifically defined matrix as compared to the comparative formulations (page 3, last paragraph and Table on page 12). None of the cited references individually or in combination suggests or discloses a matrix consisting only of a phospholipid and a support material. In contrast to the present invention, in the prior art references, the phospholipid component is used as an *adjuvant* in pharmaceuticals containing a drug (Friedman), or compounds which are factors in methionine metabolism (Kiliaan et al.) (see also page 1 bridging page 2 of the application), but not as the sole bioactive component. In view of the above amendments and discussion, applicants contend that the presently claimed invention is patentable over the cited prior art.

Applicants respectfully submit that all of claims 35-52 are now in condition for allowance. If it is believed that the application is not in condition for allowance, it is respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with any additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

By



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